Lateral flow urine lipoarabinomannan assay for detecting TB in HIV+ adults

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Credit: International Committee of the Red Cross (ICRC)

An international review team has prepared a Cochrane systematic review to assess the accuracy of a point-of-care urine test for diagnosing and screening tuberculosis (TB) in people living with human immunodeficiency virus (HIV).

TB is a leading cause of death in HIV-positive people. Conventional sputum tests for TB take time and are not always accurate in people with

HIV. A point-of-care test that does not depend on sputum evaluation, if sufficiently accurate, could help HIV-positive people who suffer high morbidity and mortality, by earlier detection of TB that may be missed by conventional sputum testing.

This review looks at accuracy of the lateral flow urine lipoarabinomannan assay (LF-LAM), a commercially available test that detects lipoarabinomannan (LAM), a component of mycobacterial cell walls, which is present in some people with active TB. The test is simple to carry out, requires no special equipment and provides a result within 25 minutes.

The review author team from Johns Hopkins University, USA; McGill University, Canada; London School of Hygiene and Tropical Medicine, UK; FIND, Switzerland; and LSTM, examined all data published up until 5 February 2015 and included 12 studies. Six of the studies evaluated LF-LAM for TB diagnosis, looking at people with HIV and TB symptoms, while the other six evaluated the test for TB screening looking at people with HIV regardless of the presence of TB symptoms.

Sensitivity indicates the percentage of patients who have a positive test and are correctly diagnosed with disease; specificity indicates the percentage of patients who are correctly identified as not having disease. In HIV-positive people with TB symptoms, LF-LAM shows an average sensitivity and specificity of 45% and 92%. Based on these results, in 1000 HIV-positive people where 30% (300 people) actually have TB, LF-FAM will identify 135 people with TB and miss the diagnosis in 165 with TB. For the 700 people who do not have TB, the test will correctly identify 644 people as not having TB, but will misclassify 56 as having TB.

However, the sensitivity of the test is higher in HIV-positive individuals with low CD4 cell counts who are at risk of life-threatening illnesses. In

patients with a CD4 ≤ 100 cells per μL, LF-LAM sensitivity was 56% versus 26% in patients with a CD4 count > 100 cells per μL.

Dr Karen Steingart from LSTM is the senior author of the review. She said: "LF-LAM, whether used for diagnosis or screening, has low sensitivity to diagnose TB. However, and this is key, in HIV-positive individuals with low CD4 counts who are seriously ill, LF-LAM may help with the diagnosis of TB." Steingart added, "the review findings should be interpreted with caution due to small number of studies and participants involved at this point." The draft of this systematic review informed the WHO policy recommendations on the use of LF-LAM for the [diagnosis](#) and screening of active TB in people living with HIV (WHO Lipoarabinomannan Policy Guidance 2015).

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